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10/032,201	12/19/2001	Gijs Van Rooijen	38814-351B	4943

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,201

Applicant(s)

Rooijen et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -1- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6/10/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-28 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-28 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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The instant application was only recently forwarded to the Examiner. Upon reviewing it, the Examiner discovered that page 1 of the specification is missing. According to MPEP 601.01(d), Applicants have three options:

- (A) accept the application as filed, without page 1;
- (B) file omitted page 1 with an oath or declaration in compliance with 37 CFR 1.63 and 37 CFR 1.64 referring to page 1, together with a petition under 37 CFR 1.182 and the accompanying petition fee set forth in 37 CFR 1.17(h), requesting the date of submission of page 1 as the application filing date; or
- (C) file a petition under 37 CFR 1.53(e) with the petition fee set forth in 37 CFR 1.17(h) alleging that page 1 was in fact deposited with the USPTO with the application papers, including any and all evidence supporting the allegation. See MPEP 503. The petition fee will be refunded if it is determined that page 1 was in fact received by the USPTO with the application papers deposited on filing.

If Applicant is willing to accept the application without page 1, an amendment of the specification is required to renumber pages of the application consecutively and to cancel any incomplete sentences caused by the absence of page 1. The amendment should be submitted in response to this Office action.

Any petition filed under part (B) or (C) above should be submitted to the Technology Center.

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Accordingly, the preliminary amendment of 29 August 2002 has been entered-in-part, without entry of the portion of that amendment relating to page 1 of the specification.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 4, 8, 15-16, and 20, drawn to nucleic acid molecules encoding fusion proteins comprising an oil body targeting protein and a thioredoxin-related protein comprising one or both of thioredoxin or thioredoxin reductase, and methods for their use to transform fungal or animal cells for the production of oil bodies containing the individual protein or a multimeric protein, classified in class 435, subclass 69.8, for example.
- II. Claims 3, 17-19, and 21-23, drawn to transgenic plants comprising nucleic acid molecules encoding fusion proteins comprising an oil body targeting protein and a thioredoxin-related protein, said nucleic acid molecules operably linked to seed-specific promoters, and methods for sexual crossing said plants, classified in class 800, subclass 287, for example.
- III. Claim 5, drawn to an isolated fusion protein, classified in class 530, subclass 350, for example.
- IV. Claims 6-7 and 9, drawn to isolated oil bodies, classified in class 554, subclass 227, for example.
- V. Claims 10-11 and 26, drawn to cosmetic formulations comprising oil bodies, classified in class 424, subclass 450, for example.

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- VI. Claims 10, 12 and 24, drawn to a method of using oil bodies to reduce food allergenicity, and food comprising said oil bodies, classified in class 426, subclass 601, for example.
- VII. Claims 13, 25 and 27, drawn to a method for using a fusion protein comprising an oil body protein and a thioredoxin-related protein as a pharmaceutical, classified in class 514, subclass 2, for example.
- VIII. Claim 14, drawn to a method of immobilizing an in vitro-produced enzyme complex onto isolated oil bodies, classified in class 435, subclass 183, for example.
- IX. Claim 28, drawn to a nucleic acid construct encoding an oil body protein, a protein of interest, and an oil-body-surface-avoiding linker, classified in class 536, subclass 23.4, for example.

Claim 10 will be examined to the extent that it reads on the elected invention.

The inventions are distinct, each from the other because:

Inventions I-VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The invention of Group IX requires sequences encoding an oil-body-surface-avoiding linker and a multitude of proteins of interest including hormones, antibodies, toxins, etc., each not required by the

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inventions of Groups I-VIII. The inventions of Groups I-VIII require thioredoxin-related proteins and sequences encoding them, each not required by Group IX.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and different modes of operation. Group I involves methods of fungal or animal cell transformation and culture, and regulatory elements specific thereto, each not required by Group II. Group II requires methods of plant cell transformation and plant regeneration, plant-expressible regulatory elements including seed-specific promoters, and methods for sexually hybridizing plants, each not required by Group I.

Inventions I-II and IX, and Inventions III-VIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The isolated nucleic acid molecules and transformation methods of Groups I-II and IX are not required by the isolated proteins or isolated oil bodies and methods and compositions for their use of Groups III-VIII.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process, such as a process for cosmetically treating skin.

Inventions IV and V are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a food allergen reducer and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as a method for performing enzymatic reactions in immobilized oil bodies.

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Inventions VIII and each of I-VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The method of immobilizing isolated redox fusion proteins of Group VIII is not required by any other Group, and the oil body protein/thioredoxin-related protein fusion proteins of the other Groups are not required by Group VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, classification, and fields of search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 22, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~/1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.